Noveome Biotherapeutics, Inc. Receives FDA Notification to Proceed with its Phase 1-2 Clinical Trial in Treatment of NEC

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Noveome Biotherapeutics, Inc. Clinical Stage Biopharmaceutical

PITTSBURGH, PA, UNITED STATES, December 11, 2023 / EINPresswire.com/ -- Noveome Biotherapeutics, Inc. Receives FDA Notification to Proceed with its Phase 1-2 Clinical Trial Evaluating ST266 in the Treatment of Necrotizing Enterocolitis in Premature Infants

Pre-clinical results suggest that ST266 may be effective in both preventing and treating Necrotizing Enterocolitis; first potential breakthrough therapy in over 30 years.

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>
> *Dr. Karin Potoka, Chief Medical Officer*

Noveome Biotherapeutics, Inc., a clinical stage Pittsburgh-based biopharmaceutical company focused on developing next-generation biologics for the treatment of rare pediatric diseases with high morbidity and mortality, today announced that it has received notification from the U.S. Food and Drug Administration (FDA) that it may proceed with its Phase 1-2 clinical trial evaluating the safety and efficacy of its novel biologic ST266 in Necrotizing Enterocolitis (NEC). In connection with the FDA notification, the Company anticipates a closing on at least an additional $13.5 million of Series E convertible preferred stock financing from MAK Capital and other existing investors to supplement the $22.1 million raised to date in the Series E financing announced in August of this year. The additional funding is expected to be completed by December 20, 2023. Proceeds from the financing will be primarily used to support the conduct of the NEC clinical trial.

The planned Phase 1-2 clinical trial is expected to enroll approximately 36 patients with NEC of which 24 patients will receive ST266 in addition to standard of care and 12 will receive standard of care only. Patients will be enrolled upon diagnosis of NEC and, if randomized to the treatment group, will be treated with intravenously administered ST266 once-daily for 10 days. Key endpoints are intended to demonstrate safety and tolerability as well as to assess preliminary efficacy by evaluating clinical outcomes such as time to resolution of pneumatosis, time to return to full feeding, reduction of surgical intervention, and effect on long term neurodevelopment outcomes. First patients are expected to be enrolled in early Q1 2024. The FDA has previously granted both Rare Pediatric Disease Designation (RPDD) and Orphan Drug Designation (ODD) to ST266 for the treatment of NEC.

“The FDA’s clearance of our Investigational New Drug application for Phase 1-2 testing in premature infants with NEC is an important milestone for Noveome, and represents a new paradigm in the treatment of NEC patients,” stated Patrick Welch, CEO of Noveome. “The additional funding will enable the company to continue our clinical progress to address this critical medical need in the most vulnerable patient population.”

“NEC is an often fatal inflammatory gastrointestinal disease that can develop in premature infants,” said Dr. Karin Potoka, Chief Medical Officer of Noveome. “There are currently no pharmacological therapies approved specifically for the treatment of NEC, making it a major unmet need globally, and we are excited about the potential for ST266 to revolutionize both the prevention and the treatment of this devastating disease.”

About ST266

ST266 is a cell-free sterile biologic solution containing hundreds of proteins and other factors at physiologic levels. It is made by culturing a novel population of human amnion-derived cells. Using a proprietary culturing method, these cells produce a unique array of growth factors and cytokines, known as the secretome, which promote cellular survival and reduce inflammation. Extensive preclinical studies have shown that ST266’s multiple components result in a variety of anti-inflammatory and neuroprotective responses. A drug master file has been submitted to the FDA, supporting all ST266 investigational new drug (IND) applications.

About Necrotizing Enterocolitis

Necrotizing Enterocolitis (NEC) is a devastating disease caused by inflammation of the intestines observed primarily in premature and very low birth weight babies (VLBWB). The inflammation can result in an overwhelming infection which quickly becomes a medical emergency and often requires surgery as a life-saving measure. Necrotizing enterocolitis affects 2% to 10% of all premature infants worldwide. Overall, the mortality from NEC ranges from 10% to 50%. Treating and managing premature infants with NEC is responsible for over $5 billion annually in Neonatal Intensive Care Unit (NICU) expenditures in the United States. Babies that do survive can be left with life-long intestinal complications and are also at increased risk for neurodevelopmental

delays with cognitive, visual, and motor impairments.

About Noveome Biotherapeutics, Inc.

Based in Pittsburgh, Noveome Biotherapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing next-generation biologics for a wide range of indications including for the treatment of rare pediatric diseases with high morbidity and mortality. Noveome has completed a Phase 2 open-label clinical trial that demonstrated the benefit ST266 had in healing persistent corneal epithelial defects (PEDs). ST266 also completed a Phase 1 open-label clinical trial establishing the safety of ST266 in intranasal transcribriform delivery from nose-to-brain and eye, and a Phase 1 clinical trial establishing the safety of intravenously administered ST266 in COVID-19 patients. For more information, visit www.noveome.com.

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